Lab Quality Assurance with EP Evaluator

Accelerate and improve performance verification studies across your lab

Your lab is confronted with constant resource pressure and demands to do more with less. Instrument performance validation is an essential part of ensuring your lab produces accurate results and is compliant with regulatory requirements. But, it's also another demand that distracts resources away from the critical task of processing patient results.

When labs can accelerate the pace of method and instrument validation and have increased confidence in the results, they can protect the regulatory reputation of their lab and devote more time to producing results for patients.

Lab Quality Assurance with EP Evaluator helps labs automate and accelerate performance verification studies across your lab, including precison, linearity, and correlation analyses. EP Evaluator evaluates and measures clinical laboratory performance, and provides clear, concise, 'inspector-ready' reports meeting CLIA, The CAP, The Joint Commission, and COFRAC requirements.

Why EP Evaluator?

Adheres to CLIA, The CAP, The Joint Commission, and COFRAC requirements

Performs calculations for 100+ studies simultaneously

Generates inspector-ready reports

Integrates with Instrument Manager to automate data import

Streamlined instrument performance verification studies

Lab Quality Assurance with EP Evaluator delivers:

- **Simplified performance verification:** Accelerate instrument validation - including precision, linearity, and correlation analytics - by performing calculations for 100+ studies simultaneously, and simplify instrument-to-instrument comparison
- **Clear, concise, 'inspector-ready' reports:** Save time and build confidence with professional, data-driven, automated reports to support inspection needs
- **Compliance with common regulatory specifications:** Designed by a board-certified clinical chemist, EP Evaluator meets CLIA, The CAP, The Joint Commission, and COFRAC requirements
- **Integration with Instrument Manager for automated data import*:** Integrate seamlessly to automate instrument data input, saving hours or even days in data entry and reporting of thousands of results
- **Adherence to major CLSI protocols:** Implements eight CLSI protocols, including EP5-A, EP6-A, EP7-A, EP9-A, EP10-A, EP12-A, C28-A2, and GP10-A
- **Comprehensive statistical calculations and industry standard procedures:** 30+ statistical modules, meeting The CAP and CLIA '88 requirements for validating and evaluating methods

* Available with EP Evaluator Pro

Ready for improved performance verification studies with EP Evaluator?

Contact Us

	Regulatory Requirements				EE Versions	
	CLIA '88	The CAP	TJC	COFRAC	Standard	Professional
Features						
Composite Reporting	-	-	-	-	●	●
Project Management	-	-	-	-	●	●
Import Data from IM and via ODBC	-	-	-	-	-	●
Security Audit Trail	-	-	-	-	-	●
User Accounts for Network Security	-	-	-	-	-	●
Accuracy and Linearity						
Clinical Linearity, Calibration Verification	✓	✓	✓	O	●	●
Reportable Range	✓	✓	✓	O	●	●
Simple Accuracy	✓	✓	-	-	●	●
Trueness	-	-	-	-	●	●
CLSI EP6 Linearity	-	-	-	-	●	●
Method Comparison						
Alternate (Routine Quantitative)	✓	✓	✓	O	●	●
CLSI EP9 A2 Method Comparison	-	-	-	-	●	●
CLSI EP9 A3 Method Comparison	-	-	-	-	●	●
Two Instrument Comparison	-	✓	✓	✓	●	●
Multiple Instrument Comparison	-	✓	✓	✓	●	●
Qualitative / Semi-Quantitative	✓	✓	✓	O	●	●
POC Glucose	-	-	-	-	●	●
Hematology Studies	-	-	-	-	●	●
Precision						
Simple Precision	✓	✓	✓	✓	●	●
CLSI EP5 Precision	-	-	-	-	●	●
Reference Interval						
Establish	✓	✓	✓	✓	●	●
Verify	✓	✓	✓	✓	●	●
ROC Plots	-	-	-	-	●	●
Sensitivity						
Limits of Blank (Analytical) *	✓	-	✓	O	●	●
Limits of Quantitation (Functional)*	-	-	-	O	●	●
Lab Management						
Cost per Test	-	-	-	-	●	●
Incident Tracking	-	-	-	-	●	●
Inventory Management**	-	-	-	-	●	●
Competency Assessment	-	-	-	-	●	●
Coagulation						
Geometric Mean and VRI	-	✓	✓	-	●	●
PT/INR Method Comparison	-	✓	✓	-	●	●
Manual INR Check	-	✓	-	-	●	●
Factor Sensitivity (FS)	-	-	-	-	●	●
Other						
Performance Standards (TEa)	-	-	-	-	●	●
Carryover	-	✓	-	✓	●	●
CLSI EP10 - Preliminary Evaluation	✓	✓	✓	-	●	●
Interference (CLSI EP7) *	✓	✓	✓	O	●	●
Six Sigma Metrics	-	-	-	-	●	●
Average of Normals	-	-	-	-	●	●
Stability	-	-	-	-	●	●
Histogram and Descriptive Stats	-	-	-	-	●	●

✓ Addresses requirements by regulatory organization | O Addresses suggestions by regulatory organization

* Evidence can be provided from vendor or laboratory | ** Barcode scanners are compatible with physical servers only.

Both Standard and Professional versions include a capability for concurrent, multiple user access that is especially useful for sites with multiple quality assurance leaders or multi-site users

System Requirements for EP Evaluator®

Operating Systems	Windows Server 2016 Windows Server 2019 Windows Server 2022 Windows 10 (EE11.3 and up) Windows 11
Memory Specifications	A minimum of 128 MB of RAM for the application
Hard Disk Specifications	Minimum of 200 MB for non-network, single-user implementation Minimum of 1 GB for networked, multi-user implementation
Other	Monitor (1024 x 768 minimum resolution), keyboard, mouse and local or networked printer Adobe Reader or compatible program

System Requirements for data acquisition

EP Evaluator®	EP Evaluator 11.0 or later of Standard or Professional version for ODBC Connection EP Evaluator 12.3 or later of Professional version for connection without ODBC
Instrument Manager™	Instrument Manager™, version 8.08 or later with Specimen Management and ODBC
Laboratory Process Manager	Laboratory Process Manager (LPM) version 5.6.2 or later Microsoft ODBC driver for Oracle 2.575.1117.00 or later

Product Training

Webinars and workshops on selected EP Evaluator topics are available. Consult resources.epevaluator.com for further information.